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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SLOBODYANSKY, ELIZABETH	
ART UNIT	**PAPER NUMBER**
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,224	LASSEN, SOREN FLENSTED	
	Examiner	Art Unit	
	Elizabeth Slobodyansky, PhD	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) *32-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-31 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-41 are pending.

Election/Restrictions

Claims 32-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups II-XXIV, there being no allowable generic or linking claim. Election was made in the reply filed on December 21, 2007.

Applicant's election of Group I, *i.e.* claims 22-31 and 39-41, SEQ ID NO:28, in the reply filed on December 21, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2 references on PTO-1449 filed December 12, 2005 are lined through because the provided information is insufficient to identify the reference.

Specification

The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code at pages 1 and 6. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s). In particular, an octapeptide [QSHVQSAP] and a tetrapeptide [QSAP] are stated at least at page 14, line 21, but are not identified by sequence identification numbers, even though their sequence identifiers are available in the sequence listing. Applicant's attention is directed to 37 CFR 1.821, which states:

> (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Thus, each time that reference is made to an amino acid sequence having 4 or more amino acids, or a nucleotide sequence having ten or more nucleotides, in the specification or in the claims, it should be accompanied by the sequence identifier "SEQ ID NO:".

Claim Objections

Claims 22-31 and 39-41 are objected to as reciting a non-elected subject matter.

Claim 26 is objected to because a period at the end of the claim is missing.

Claim 40 is objected to because "9%" is typed on line 5, where "90%" is intended.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22(c), with dependent claims 23-31, is drawn to a variant of the mature part of the polypeptide of SEQ ID NO:28, comprising a substitution, deletion, extension, and/or insertion of one or more amino acids. Because the number of allowed substitutions, deletions, extensions, and/or insertions is not limited, claim 22 encompasses the genus of polypeptides having protease activity both naturally occurring and man made having any structure and properties defined by enzymatic function only.

In the instant specification the diverse and variable genus of polypeptides having protease activity that are variants of the mature part of the polypeptide of SEQ ID NO:28 is represented by a single species of the mature part of the polypeptide of SEQ ID NO: 28. The specification teaches that pro-region of the polypeptide of SEQ ID NO:28 has

the amino acid sequence of SEQ ID NO:30 (page 59, lines 12-14). SEQ ID NO: 30 is 100% identical to residues (-166) – (-1) of SEQ ID NO:28.

The specification fails to describe any other representative species of the claimed genus by any identifying characteristics or properties other than the functionality of having protease activity and does not disclose the structure: function correlation common to all members of the genus. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 22-31 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide having protease activity that is the mature part of the polypeptide of SEQ ID NO:28, does not reasonably provide enablement for a polypeptide having protease activity comprising an amino acid sequence having no defined identity to SEQ ID NO:28 or that is at least 70%, 80% or 90% identical to the amino acid sequence of the mature part of the polypeptide of SEQ ID NO:28. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of

direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, *e.g.* multiple substitutions.

The specification does not support the broad scope of the claims which encompass a polypeptide having protease activity comprising an amino acid sequence having no defined identity to SEQ ID NO:28 or that is at least 70%, 80% or 90% identical to the amino acid sequence of the mature part of the polypeptide of SEQ ID NO:28 because the specification does **not** establish: (A) regions of the protein structure which may be modified without affecting a protease activity; (B) the general tolerance of protease to modification and extent of such tolerance; (C) a rational and predictable

scheme for modifying any protease residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Without sufficient guidance, beyond that provided, obtaining a polypeptide having protease activity comprising an amino acid sequence having no defined identity to SEQ ID NO;28 or that is at least 70%, 80% or 90% identical to the amino acid sequence of the mature part of the polypeptide of SEQ ID NO:28 is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).

While claims 23-25, 30 and 31 limit pro-region and signal peptide, they are included in the rejections because the claims are drawn to a polypeptide comprising the mature part of SEQ ID NO:28. The way the claimed polypeptide is obtained does not affect the patentability because it resides in the product not in the process of making thereof.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22(c), with dependent claims 23-31, recites the limitation "the segment". There is insufficient antecedent basis for this limitation in the claim. Further, Claim 22(c) recites "extension" of amino acids. The term is unclear because an amino acid cannot be extended.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22-31 and 39-41 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to "a secreted mature polypeptide". Said polypeptide is secreted in Nature and as its product is unpatentable. Amending the claims to recite "an isolated mature polypeptide" is suggested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-31 and 39-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,179,630. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 22-31 and 39-41 are drawn to a polypeptide having protease activity and an amino acid sequence comprising the mature part of SEQ ID NO:28 (residues 1-188, *supra*). Claims 1-12 are drawn to a polypeptide having protease activity and having an amino acid of residues 1-188 of SEQ ID NO:2. SEQ ID NO:2 of US 7,179,630 is 100% identical to SEQ ID NO:28 of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

January 31, 2008